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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,878	02/07/2007	Reto Luginbuehl	0002586USU/4122	1424

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EXAMINER	
HOBAN, MELISSA A	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
07/20/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,878	LUGINBUEHL, RETO	
	Examiner	Art Unit	
	MELISSA HOBAN	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-21,23-29 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-21,23-29 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/25/2010 has been entered. Claims 1, 3-21, 23-29, and 32-36 are currently pending in this application.

Response to Arguments

2. Applicant's arguments with respect to the newly amended and newly added claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

3. Claim 14 is objected to because of the following informalities: Claim 14 recites "The device according to claims 9", which appears to be a misspelling of the word -- claim --. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-6, 8-10, 15, 16, 19-21, 23-29, 32, 33, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,511,511 B1 to Slivka et al. (Slivka), as evidenced by US Patent No. 5,607,474 to Athanasiou et al. (Athanasiou).

Regarding at least claims 1, 16, 19-21, and 32-33

Slivka teaches a fiber-reinforced, polymeric implant material useful for tissue engineering and method of making the same (abstract). The implant material preferably comprises a polymeric matrix, preferably a biodegradable matrix having fibers substantially uniformly distributed therein in predominantly parallel orientation (figs. 1 and 2), meaning that greater than fifty percent of the total length of the totality of the fibers, and preferably greater than 75%, are oriented in the same direction or within about 20 degrees, more preferably within about 15 degrees, of the same direction (col. 3, lines 37-43).

In preferred embodiments, porous tissue scaffolds are provided which facilitate regeneration of load-bearing tissues such as articular cartilage and bone (col. 1, lines 62-67 and col. 2, lines 1-3). The scaffold may be implanted into humans or animals to provide support for physiological loads applied parallel to the predominant direction of orientation of the fibers. For example, in an osteochondral site on the femoral condyle, the primary direction of loading is perpendicular to the surface of the cartilage. The oriented fibers act like struts in a bridge support to provide strength and stiffness to the pore walls of the scaffold and provide characteristic columnar pore architecture especially suitable for cell in growth (col. 2, lines 4-16).

Slivka also teaches that the implant material of the invention may be used as one phase of a multiphase implant (col. 4, lines 36-38) that may include a solid film, a cartilage phase, a bone phase, etc. (col. 9, lines 20-25). Such a multiphase implant/tissue carrier includes a first phase comprising a first porous biodegradable polymeric material, the first phase having a predetermined porosity and a second phase comprising a second porous biodegradable polymeric material, the second phase having a predetermined porosity, wherein the first material is bonded to the second material in a fairly rigid, yet porous multi-phase structure, as evidenced by Anthansiou (col. 7, lines 19-21 and claim 8). As can be seen by the figures of Anthansiou, the multiphase implant (prosthetic device), in which the fiber layer of Slivka can be used as one of the phases, inherently comprises at least one layer having at least partially oriented fibers, a round, cylindrical, or conical base component to anchor said at least on layer of fibers in subchondral environment, and a stabilization area provided between said at least one layer having fibers and said base component (see annotated figure 1 of Anthansiou below).

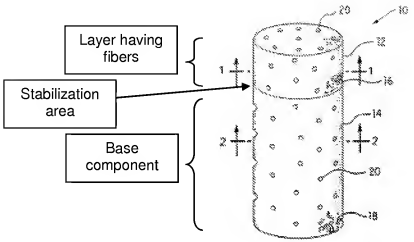

FIG. 1

Slivka also meets the limitation that the fibers are aligned essentially in parallel to the insertion axis of the prosthetic device that is in a direction perpendicular to a top surface of the base component and the fibers form a brush-like structure, at least to the same extent as applicant's. Further, more than 50% of the fibers taught by Slivka are aligned essentially in parallel to the insertion axis of the device, as claimed.

The examiner notes that the claimed stabilization area appears to be met by any portion of the implant between an arbitrarily located layer having partially oriented fibers and a base component. It is understood by the examiner that the stabilization area taught by Slivka, as evidenced by Anthansiou, meets the limitation of a porous zone comprising at least one layer having a thickness of 1 nm to 1 mm, as claimed by applicant. The use of functional language throughout the claims (see claims 1, 32, and 33, for example) is also noted. Applicant is reminded that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural

limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Since the device of Slivka, as evidenced by Anthansiou, meets the claimed structural limitations and is at least fully capable of performing the claimed functions, it meets the claim. It is further maintained by the examiner that the limitations "essentially" and "brush-like" are broad.

Regarding at least claims 3-5

Slivka teaches that the fibers may be made of any suitable material and are preferably synthetic fibers of a length short enough not to interfere with processability and have a diameter between about 5 μm and about 50 μm (col. 2, lines 59-67 and col. 3, lines 1-7), which is within the claimed diameter range.

Regarding at least claims 9, 10, and 15

The examiner takes the position that since the implant of Slivka is meant for use in a variety of tissue engineering applications, including osteochondral defect repair, partial and full thickness cartilage defect repair, bone graft substitute, etc (col. 2, lines 41-45), the limitation that the base component comprises a material used as a bone substitute, is inherently met. Slivka also teaches that the biodegradable matrix used as the implant material may be biodegradable polymers or other materials known in the art (col. 3, lines 26-35). Further, it is clear from Slivka that the material is highly porous with interconnecting pores (col. 3, lines 47-51).

Regarding at least claims 6, 8, and 36

Slivka teaches that the scaffold has a mass degeneration rate which is a property that may be tailored for optimal performance. As known to the art, according to Slivka, mass degradation rate may be controlled by type of biodegradable polymer, molecular

weight, and degree of crystallinity. For repair of articular cartilage, it is preferred that at least about 90% of the scaffold be resorbed by between eight and 26 weeks after implantation (col. 7, lines 59-67). To make the fiber-reinforced scaffolds of the invention, the matrix polymer and fibers are selected, the matrix polymer is dissolved in an appropriate amount of solvent, and the fibers are immersed in a non-solvent of the polymer. Once the matrix polymer is completely dissolved and the fibers are well dispersed in the non-solvent, the two are added together and stirred which should be continued until an opaque, cohesive gel has precipitated and can be lifted out onto a non-stick surface. The gel is then kneaded to disperse the fibers uniformly within the gel and eventually, the gel is shaped according to the type of mold being used, which depends on the orientation of the fibers desired (col. 8, lines 3-10, 22-28, and 44-46).

The examiner takes the position that the fibers taught by Slivka inherently have a liquid absorbing capacity in a range of 0.1% to 99.9% and that the liquid is an aqueous solution and/or body fluids, as claimed by applicant. Further, the fibers are designed to form a gel or transform to a gel-like state when absorbing liquid.

Regarding at least claims 23-29

The porous material of the invention of Slivka acts as a scaffold providing support and spaces for in growth of cells either after it has been placed within a tissue defect in the patient's body, or alternatively, the scaffold material may be pre-seeded with autologous or allogenic cells or cell-containing media before implantation. This meets the limitation of at least one externally added component which is cells of different origin being autologous, allogenous, xenogenous, transfected, and/or genetically engineered

cells, as claimed. Slivka also teaches that the implant material of the invention has mechanical properties similar to or identical to those of the tissue into which the implant is to be placed, controlled by the amount and type of fibers used (col. 4, lines 36-45). Further, Slivka, as evidenced by Athanasiou, teaches the addition of chondrocytes to form cartilage, which would inherently be present throughout the fiber layer since it is surrounded by the cartilage portion of the defect, as well as osteoprogenitor cells to accelerate the formation of bone, which would inherently be present throughout the base component since it is surrounded by the bone portion of the defect, as claimed (col. 4, lines 13-27). It is further inherent to the implant of Slivka that blood or any faction thereof is present throughout the base component, at least when the scaffold is implanted. It is also taught by Slivka that the implant can be used to deliver bioactive agents such as growth factors, antibiotics, hormones, steroids, and anti-inflammatory agents and anesthetics in timed manner (col. 4, lines 31-35). At least one of these meets the limitation of pharmaceutical compounds being contained, as claimed by applicant.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 7, 17, and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Slivka, as evidenced by Anthansiou.

Regarding at least claim 7

Slivka, as evidenced by Anthansiou, teaches the invention substantially as claimed according to claim 6. Though Slivka does not explicitly teach a range of liquid absorbing capacity of 20% to 99%, the examiner takes the position that this property is inherent to the fibers of Slivka. However, if it is not inherent, it would have been obvious to one having ordinary skill in the art at the time the invention was made to specify this range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding at least claims 17 and 18

Slivka, as evidenced by Anthansiou, teaches the invention substantially as claimed according to claim 16. Further, to treat a full thickness cartilage defect, Slivka teaches an implant 8 mm in diameter with a thickness of 2 mm as a typical size, which meets the limitation that the base component has a diameter ranging between 2 and 30 mm, or 4 and 20 mm, as well as a height being 1 to 30 mm, or between 1 to 6 mm, as claimed by applicant. If it is not inherent, it would have been obvious to one having ordinary skill in the art at the time the invention was made to specify this range, since it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

8. Claims 11-14 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slivka, as evidenced by Anthansiou, in view of US Patent No. 6,626,950 B2 to Brown et al. (Brown).

Regarding at least claims 11-14

Slivka, as evidenced by Anthansiou, teaches the invention substantially as claimed according to claim 9. Slivka also teaches that the implant material of the invention has mechanical properties similar to or identical to those of the tissue into which the implant is to be placed, controlled by the amount and type of fibers used (col. 4, lines 36-45). However, Slivka, as evidenced by Anthansiou, does not teach that the base component comprises a synthetic ceramic or a composite material.

Brown teaches a prosthetic implant having a tissue scaffold component and a fixation component that is useful in the repair/regeneration of defects present at junction sites such as articular or meniscal cartilage (col. 3, lines 13-30). The scaffold component (prosthetic device; 20) has a polymeric phase (22) and ceramic phase (base component; 24), which are mechanically interlocked at interphase region (26). Brown also teaches that the ceramic phase (base component; 24) lies adjacent to bone tissue (col. 12, lines 10-11) and may be composed of hydroxyapatite, calcium sulfates, calcium carbonates, magnesium calcium phosphates, and mixtures thereof, or of a porous polymer matrix with inclusions of short ceramic fibers (col. 6, lines 43-56). Since Brown

contemplates mixtures of the materials, it would be obvious to use a composite material comprising at least a polymer component and a mineral phase, as claimed by applicant.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the base component of Slivka, as evidenced by Anthansiou, to include specifics about the material used, in order to ensure that the implant material has mechanical properties similar to or identical to those of the tissue into which the implant is to be placed, as taught by Brown. The examiner notes that it also would have been obvious to one having ordinary skill in the art at the time the invention was made to specify these materials to be used for the base component, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Further, it is noted that the limitations of claim 12, regarding calcium phosphate, are not positively recited and are therefore given little patentable weight.

Regarding at least claim 34

Slivka, as evidenced by Anthansiou, teaches the invention substantially as claimed according to claim 1. Slivka also teaches that the fibers are substantially uniformly distributed therein in predominantly parallel orientation (figs. 1 and 2), meaning that greater than fifty percent of the total length of the totality of the fibers, and preferably greater than 75%, are oriented in the same direction or within about 20 degrees, more preferably within about 15 degrees, of the same direction (col. 3, lines 37-43).

Though Slivka, as evidenced by Anthansiou, does not explicitly teach that more than 90% of the fibers are aligned essentially in parallel to the insertion axis of the device that is in a direction perpendicular to a top surface of the base component, the examiner takes the position that it would have been obvious to modify the invention of Slivka, as evidenced by Anthansiou, to include this percentage of aligned fibers since Slivka clearly teaches that it is desirable to have any percentage higher than 75% of the fibers aligned, and particularly in view of the lack of any disclosed criticality of the claimed limitation. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to specify this range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

9. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slivka, as evidenced by Anthansiou, in view of US Patent No. 4,553,272 to Mears (Mears).

Slivka teaches the invention substantially as claimed according to claim 1. However, Slivka does not appear to teach an absolute or selective cell barrier layer.

Mears teaches an open-pored implant containing isolated daughter cells. The implant is shaped to the desired configuration for joint reconstruction or reconstruction of a portion of a joint, bone or such other use as desired (col. 2, lines 34-38). The implant pores which receive the daughter cells and contain the tissue grown therewithin during culturing and thereafter, preferably have a pore size on the order of 25 to 75 microns with 50 to 70 microns being the preferred range. For some uses where the site

of attachment is adjacent to bone, the implant may be provided with another series of pores which are larger and may be about 100 to 400 microns in size. These larger pores serve to permit ingrowth of blood vessels and adjacent osteogenic cells after implantation in the patient (col. 3, lines 55-67). Where both pore sizes are provided, it is preferred to establish a barrier between the two pore sizes so as to resist undesired commingling of the tissue generated by the daughter cells with the blood vessels and osteogenic cells which are ingrown in the patient (col. 4, lines 1-6). A barrier that serves to resist communication therebetween may be provided. If desired, the barrier may be provided in the form of a separate member which is molded or otherwise secured within the porous implant (col. 5, lines 34-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Slivka, as evidenced by Anthansiou, to include a cell barrier layer, in order to resist communication between the two different pore size areas of the implant, as taught by Mears.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA HOBAN whose telephone number is (571)270-5785. The examiner can normally be reached on Monday through Friday (8am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Thomas Sweet, at (571) 272-4761***. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov**.**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 3738

/BRUCE E SNOW/
Primary Examiner, Art Unit 3738